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09/441,857 11/18/99

DOFTY

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/0725

KENYON & KENYON  
ONE BROADWAY  
NEW YORK NY 10004

CANELLA, K

EXAMINER

1642

ART UNIT

PAPER NUMBER

DATE MAILED:

5  
07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/441,857

Applicant(s)  
Duffy et al

Examiner  
Karen Canella

Group Art Unit  
1642



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-80 \_\_\_\_\_ is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-80 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62 and 70, drawn to nucleic acids encoding wth3 protein, vectors, hosts, kits comprising probes and oligos which hybridize to wth3 protein, classified in class 536, subclasses 23.5, 24.33, 24.31 and class 435, subclasses 69.1, 320.1, 325, 252.3. Claims 7-10 and 70 will be examined with Group I to the extent that they read on nucleic acids encoding wth3 protein.
  - II. Claims 5-10, 45, 48, 51, 64 and 70, drawn to vectors comprising nucleic acids encoding RAB6 protein, kits comprising probes and oligos which hybridize to RAB6 protein, classified in class 536, subclasses 23.1, 24.33, 24.31 and class 435, subclass 320.1. Claims 7-10 and 70 will be examined with Group II to the extent that they read on nucleic acids encoding RAB6 protein.
  - III. Claims 13-16, drawn to a substantially purified wth3 protein or fragment, classified in class 514, subclass 2.
  - IV. Claim 17, drawn to a substantially purified RAB protein, classified in class 514, subclass 2.
  - V. Claims 21 and 26, drawn to an antibody which binds to wth3 protein, kit comprising said antibody, classified in class 424, subclass 130.1.
  - VI. Claim 22, drawn to a method for producing a hybridoma which secretes an anti-wth3 antibody, classified in class 435, subclass 449.
  - VII. Claims 23-25, drawn to a method for detecting wth3 protein comprising contacting a sample with anti-wth3 antibody, classified in class 435, subclass 7.1.
  - VIII. Claims 27-29 and 52-54, drawn to a method for detecting DNA methylation of the wth3 gene in a sample comprising polynucleotide hybridization, classified in class 435, subclass 6.

- IX. Claims 31-33, 37-40, 58-61 and 71-76, drawn to a method for detecting wth3 in a sample and a method of determining suitability of treatment comprising polynucleotide detection, classified, for example, in class 435, subclass 6. Claims 71-76 will be examined with Group IX to the extent that they read on wth3 detection.
- X. Claims 42-44, drawn to a method for detecting methylation state of RAB gene comprising polynucleotide hybridization, classified in class 435, subclass 6.
- XI. Claims 46, 47, 49, 50, 63-68 and 71-76, drawn to a method for detecting RAB6 and homologues comprising polynucleotide detection, classified, for example, in class 435, subclass 6. Claims 71-76 will be examined with this group to the extent that they read on RAB6 protein.
- XII. Claim 69, drawn to a method for increasing drug sensitivity of a cell comprising expression of wth3, classified in class 435, subclass 69.1. Claim 69 will be examined with Group XII to the extent that it reads on expression of wth3.
- XIII. Claim 69, drawn to a method for increasing drug sensitivity of a cell comprising expression of RAB6, classified in class 435, subclass 69.1. Claim 69 will be examined with Group XIII to the extent that it reads on expression of RAB6.
- XIV. Claims 77-80, drawn to a method for determining whether a substance increases sensitivity of a cell to a therapeutic comprising contacting a test cell which overexpresses wth3 with a therapeutic, classified, for example, in class 435, subclass 6. Claims 77-80 will be examined with Group XIV to the extent that they read on overexpression of wth3.
- XV. Claims 77-80, drawn to a method for determining whether a substance increases sensitivity of a cell to a therapeutic comprising contacting a test cell which overexpresses RAB6 with a therapeutic, classified, for example, in class 435, subclass 6. Claims 77-80 will be examined with Group XV to the extent that they read on overexpression of RAB6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-V are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups VI-XV differ in the method objectives, method steps and parameters and in the reagents used.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding wth3 protein of Invention I can be used in an in vivo mutagenesis assay.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding wth3 protein of Invention I can be used in an in vivo mutagenesis assay.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding wth3 protein of Invention I can be used in an in vivo mutagenesis assay.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding RAB6 protein of Invention II can be used in an in vivo mutagenesis assay.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding RAB6 protein of Invention II can be used in an in vivo mutagenesis assay.

Inventions II and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid encoding RAB6 protein of Invention II can be used in an in vivo mutagenesis assay.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-wth3 antibody of Invention V can be used to raise an antiidiotypic antibody.

Inventions VI and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the anti-wth3 antibody of Invention V can be recombinantly expressed in non-lymphoid cells.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent

subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

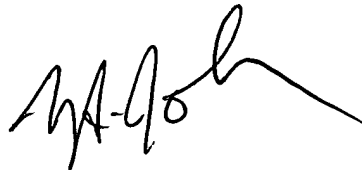
3. Because of the complexity of the claims, telephonic restriction was not attempted.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
July 17, 2000



NANCY A. JOHNSON, PH.D.  
PRIMARY EXAMINER